REMARKS/ARGUMENTS

The communication responds to the Office Action of January 2, 2008 in which the Examiner rejected claims 32-45 under 35 U.S.C. § 112 and claims 19, 23-25, 27-31, 32, 36-28 and 40-45 under 35 U.S.C. § 103(a). Claim 32 has been amended herein solely to correct the antecedent basis of "mixture". No new matter has been added by way of this amendment.

Claim Rejections under 35 U.S.C. § 112

Claims 32-45 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 has been amended herein to recite that the addition of a filler to the rice bran oil provides a mixture. The rejection being now moot, applicants respectfully request the rejection be withdrawn.

Claim Rejections under 35 U.S.C. § 103(a)

Claims 19, 23-25, 27-31, 32, 36-28 and 40-45 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama (US 6,485,760) in view of White (US 5,431,916) and McPeak (US 6,303,586).

This rejection is overcome for at least the following reasons.

The Combination Made By The Office Does Not Provide All The Elements Of The Claims

As noted in the response to the previous Office Action, neither Matsuyama, White nor McPeak disclose all the limitations of claims 19 and 32 from which all other claims depend. Therefore, the rejection over Matsuyama in view of White and McPeak is in error and should be withdrawn.

Matsuyama Teaches A Total Extract Of Lagerstroemia Speciosa

Specifically, Matsuyama discloses a method of inhibiting an increase in blood sugar level comprising a total extract of *Lagerstroemia speciosa* leaves in an aqueous or aqueous ethanol solution. In particular, Matsuyama states "[I]t is considered that the activity of the composition of the present invention in inhibiting an increase in, or lowering a human blood sugar level is caused by the interaction of a specific content of corosolic acid in the concentrate **and** extracted components of leaves of Lagerstroemia Speciosa, Linn. or Pers." Col. 2. lines 57-63, (emphasis added). Further, Matsuyama explicitly states, [I]n the composition of the present invention, those components of the leaves of Lagerstroemia Speciosa, Linn. or Pers. which are other than corosolic acid also have an effect on the activity, and ***it is required*** to take account of components to be extracted and a concentrating method and condition *with regard to the other components*." Col. 3, lines 21-26 (emphasis added). Thus, contrary to the Office's assertion that Matsuyama teaches a composition of corosolic acid, he does not. Matsuyama teaches a composition comprising a total extract of the water/ethanol soluble components, which include corosolic acid, but which is also required to take account of the other soluble components of the leaves. Thus, not only does Matsuyama not teach corosolic acid, Matsuyama teaches against the use of a composition that does not include the other ***required*** extractable components of Lagerstroemia speciosa. For this reason alone, the rejection over Matsuyama is overcome and should be withdrawn.

In addition, Matsuyama does not discuss making a formulation for a soft gel. Matsuyama does not describe using rice bran oil as a carrier. Matsuyama does not describe adding a filler to the rice bran oil carrier and Matsuyama does not describe encapsulating the mixture in a soft gel capsule.

McPeak Does Not Disclose An Oil

The Office states that McPeak "beneficially teach rice bran oil to control blood glucose levels." This is incorrect. In fact, McPeak specifically teaches a "stabilized" rice bran that is treated to deactivate any lipases present and then "dried" and/or "ground" to form a powder. Col. 5, line 38 to Col. 6, line 37. "The insoluble fraction is collected and then dried on a belt dryer, and subsequently ground into a powder. . . . The aqueous material is pumped to a drum dryer and then dried. This dried aqueous portion produces the stabilized rice bran solubilized

fraction." Col. 5, lines 47-53. Thus, in fact, contrary to the Offices' assertion, McPeak does not teach rice bran oil. Therefore, McPeak does not provide rice bran oil as *required* by the instant claims and as purported by the Office. For this reason alone, the rejection in view of McPeak is overcome and should be withdrawn.

The Combination With McPeak Would Destroy The Invention

Further, while the Office erroneously alludes to the rice bran oil being in liquid form, according to McPeak, the liquid is provided by mixing the dried "stabilized rice bran" with water. The addition of water into a soft gelatin capsule would destroy the capsule. Therefore, the "liquid" form of stabilized rice bran taught by McPeak would destroy the utility of the instant invention. Therefore, for this reason alone, the rejection in view of McPeak is overcome and should be withdrawn.

White Teaches Against The Combination Made

The Office further cites to White for the proposition that White teaches "that soft gelatin capsules containing pharmaceutical actives provide an excellent delivery of pharmaceutical actives because they are the preferred form for accurate and uniform delivery of pharmaceutical actives as well as they are convenient, portable and easy to swallow." Office Action at page 4. However, as discussed in the previous Office Action, White teaches the use of solvent systems comprising triesters paired with polyvinylpyrrolidone for acid actives contained within the soft gelatin capsule. Further, White teaches that when the actives are acids, they react with hydroxylated and polyhydroxylated solvents as well as plasticizers used to form the gelatin capsule. These reactions both degrade the actives and degrade the soft gelatin capsule. Therefore, according to White, one would not put corosolic acid in a gel capsule lest it react with the solvent degrading the corosolic acid or lest it react with the plasticizers used in making the gel capsule thereby degrading the capsule. Therefore, for this reason alone, the rejection in view of White is overcome and should be withdrawn. Applicant's respectfully request same.

In view of the preceding, the rejection of claims 19, 23-25, 27-31, 32, 36-38 and 40-45 under 35 U.S.C. 103(a) over Matsuyama in view of White and McPeak is overcome at least, because, none of the cited references teach the use of corosolic acid, none teach the use of rice

bran oil, and none teach a filler. Further, Matsuyama specifically teaches against a composition that does not include other extractable **required components** of Lagerstroemia speciosa, while White teaches against inclusion of acidic actives in soft gels unless they are provided in a solvent system comprising triesters paired with polyvinylpyrrolidone. Therefore, the rejection is overcome and should be withdrawn. Applicants respectfully request same.

Claims 20-22 and 33-35 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama (US 6,485,760) in view of White (US 5,431,916) and McPeak (US 6,303,586) as applied to claims 19, 23-25 and 27-31 above and further in view of US Patent 3,683,088 to Walter A. Gregory, denoted by the Office as "Walter" and Dickinson (US 3,66,509) and LaGrone (US 6,407,068).

The rejection of claims 20-22 and 33-35 is overcome at least for the following reasons.

First, Applicants point out that claims 20-22 and 33-35 depend from claims 19 and 32 respectively. The addition of Walter, Dickinson and LaGrone, do not cure the deficiencies of Matsuyama, White and McPeak. Further, Walter, Dickinson and LaGrone are cited for the proposition of teaching soft gel capsules with bees wax and silica respectively. Further, while the, as discussed above, while the base claims have multiple elements not found in the references cited by the Office, Applicants point out that Walter, Dickinson and LaGrone are not in the same field of art as the instant invention and therefore lacking any teaching for doing so there would be no motivation for their combination with any of the preceding documents.

Specifically, applicants point out that Walter is explicitly directed to the use of compositions of 2H-4,9-ethanobenzisoindolones for relieving pain in mammals. Walter in no way discusses compositions for treatment of blood sugar concentrations nor even to uses of corosolic acid but specifically toward the administration of 2H-4,9-ethanobenzisoindolones and its derivatives for pain relief. Thus, there is an utter lack of motivation to combine "Walter" with any of the aforementioned references either for the administration of corosolic acid or to manage blood sugar concentrations. Similarly, Dickinson is directed to the use of 1-carbamoylpyrazole-4-sulfonamides having anti-inflammatory properties. Dickinson is devoid of any mention of diabetes, blood sugar or corosolic acid. Thus, there is no motivation to combine either Walter or Dickinson with any composition for use in treating diabetes or managing blood sugar and

further, no reason to use the compounds taught in Walter or Dickinson in combination with corosolic acid. Therefore, for this reason alone, the rejection of claims20-22 and 33-35 in view of "Walter" is overcome and should be withdrawn. Applicants respectfully request same.

The Office Mischaracterizes LaGrone

The Office states "LaGrone beneficially teach silica for the prevention of diabetes whereas silica would intrinsically control blood glucose levels when preventing diabetes. (see, e.g., col. 4, lines 11-14.)" In fact, LaGrone is specifically directed to "Methods of treating humans with diseases characterized by high secretion of cytokines from macrophage cells." (see, Title). Specifically, this document is concerned with treating individuals suffering from HIV. The lines referred to by the Office merely cite to an article by Oschilewski from 1985 entitled "Administration of silica prevents diabetes in BB-rats". Thus, the Office's contention that "LaGrone beneficially teach silica for the prevention of diabetes whereas silica would intrinsically control blood glucose levels when preventing diabetes." is completely lacking in support. Further, applicants point out that there is an utter lack, in the citation, describing how the silica is administered, at what doses the silica was administered, how the diabetes was induced and whether silica is effective in treating diabetes in other animals, or indeed other strains of rats.

Further, judging from the date of the Oschilewski article, it is certainly questionable whether silica has been found effective in treating diabetes in any other preparation. Further, it is not apparent that silica is currently considered an efficacious treatment for diabetes. Or presumably the Office would have provided a reference that actually did "beneficially teach silica for the prevention of diabetes whereas silica would intrinsically control blood glucose levels when preventing diabetes." Therefore, there is no motivation for anyone reading LaGrone to add silica to a soft gel for the purpose of controlling blood sugar levels. In fact, because LaGrone is direct to methods of treating HIV, one of skill in the art would not be directed to LaGrone for the purpose of seeking guidance or soft gel capsules, corosolic acid or diabetes. Thus, lacking any motivation, LaGrone would not be combined with the preceding references, which in any case do not teach the independent claims from which claims

Claims 26 and 39 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Matsuyama (US 6,485,760) in view of White (US 5,431,916) and McPeak (US 6,303,586), alter (US 3,683,088), Dickinson (US 3,66,509) and LaGrone (US 6,407,068) as applied to claims 19-25 and 27-30 in further view of Shanmuyasundam et al (US 5,980,902).

First, Applicants wish to thank the Examiner for recognizing that the composition of the instant invention comprising corosolic acid, rice ran oil, yellow bee's wax and silica contained within a unitary soft gel capsule for maintaining of lowering blood sugar levels is an improvement on previous art as stated in the Office action at page 8. However, as discussed above, neither Matsuyama, White, McPeak, Walter Dickinson nor LaGrone combined provide all the elements to any of the claims..

Claims 26 and 39 depend from claim 19 and 32. As discussed above, the combination of Matsuyama, White and McPeak do not disclose all the elements of the present invention and further, teach against their inclusion with each other. The inclusion of Shanmuyasundam et al. does not cure the deficiencies of Matsuyama, White and McPeak. Therefore, the rejection of claims 26 and 39 in view of Shanmuyasundam is overcome. Further, Shanmuyasundam is cited for the proposition that it "beneficially teach an extract of Gymnema sylvestre for controlling blood sugar to prevent obesity. (see, e.g. column 3, lines 16-20)" This characterization of Shanmuyasundam is inapposite at best. The citation referred to by the Office states, "U.S. Pat. No. 4761,286 discloses the use of an extract of Gymnema sylvestre to inhibit intestinal glucose absorption thereby decreasing the amount of caloric intake and preventing obesity." Shanmuyasundam, further, does not provide any motivation to combine it with any other references, does not teach soft gels and does not teach a combination with corosolic acid. For at least these reasons, the rejection of claims 26 and 39 over Matsuyama, White, McPeak, Walter Dickinson nor LaGrone further in view of Shanmuyasundam is overcome and should be withdrawn. Applicants respectfully request same.

Conclusion

This application now stands in allowable form and reconsideration and allowance is respectfully requested.

This response is being submitted on or before May 2, with the required fee of $60 for a 1-month extension of time, making this a timely response. It is believed that no additional fees are due in connection with this filing. However, the Commissioner is authorized to charge any additional fees, including extension fees or other relief which may be required, or credit any overpayment and notify us of same, to Deposit Account No. 04-1420.

Respectfully submitted,

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